UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

UNITED STATES *ex rel.* KEVIN N. COLQUITT,	)	
Plaintiff	)	**Civil Action No. 3:06-cv-01769-M (BMGL)**
v.	)	
ABBOTT LABORATORIES, et al.	)	
Defendants.	)	

JOHNSON & JOHNSON AND CORDIS CORPORATION
MEMORANDUM OF LAW IN SUPPORT OF MOTION TO DISMISS
PURSUANT TO FRCP 12(b)(1), 12(b)(6) and 9(b)

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Defendants Johnson & Johnson, Cordis Endovascular and the Cordis Corporation (all hereinafter referred to as "Cordis"), by and through their undersigned counsel, hereby move this Court pursuant to Federal Rule of Civil Procedure 12(b)(1) to dismiss with prejudice the Relator's Third Amended Complaint for lack of jurisdiction or, in the alternative, for leave to conduct limited jurisdictional discovery to determine whether this Court has subject matter jurisdiction under the False Claims Act over Johnson & Johnson and Cordis as named defendants in this action. Cordis believes that the jurisdictional issues may be determined by reference to the allegations and related materials presented to the Court by the parties in this action.

If the Court finds, however, that Relator has presented a genuine question of fact as to whether he may be an original source of the allegations against Cordis under the False Claims Act (FCA), Cordis seeks discovery into the existence and sufficiency of Relator's pre-filing voluntary disclosures to the Department of Justice (DOJ) as well as the opportunity to determine via deposition testimony the information relating to Cordis presented to the government by the Relator at the time of the filing of the original complaint in this action on or before September, 2006.

Cordis further asserts that this action, if properly within the jurisdiction of this Court, must be dismissed with prejudice under Federal Rules of Civil Procedure 12(b)(6) and 9(b) for failure to state an actionable claim; and, for failure to plead fraud with sufficient legal particularity as to Cordis. Johnson & Johnson and Cordis Endovascular further seek dismissal from this action for the additional reason that both entities are improper parties.

INTRODUCTION

Cordis Corporation is a wholly-owned subsidiary of Johnson & Johnson. It serves the health care community as a manufacturer and supplier of interventional medical products that are used by physicians in the treatment of cardiovascular, endovascular and biliary duct (liver)

diseases that gravely afflict, in the United States alone, over eight (8) to twelve (12) million patients annually. Cordis has pioneered the use of minimally invasive, non-surgical products, such as stents, catheters, and guidewires, for interventional medicine for well over fifty (50) years and has sought and received regulatory approval for the manufacture and sale of over 350 stent products in the United States, including the subset of Cordis stents that are the subject of the allegations in this action. Though the lengthy complaints in this action selectively omit relevant and publicly-available regulatory history, Cordis first received FDA pre-market approval (PMA) for a vascular stent in 1991 and since that time has received additional PMA and 510(k) clearances for its stents for use in the biliary and vascular systems in addition to approvals and clearances for a host of other vascular products used in vascular patient procedures.[1]

At issue in this action is a theory that the indisputably lawful medical use of biliary stents in peripheral vascular disease procedures by thousands of hospitals and corresponding interventional physicians and surgeons in the United States since at least the late 1990s is somehow an undisclosed fraud on the United States public health and fiscal agencies, the Food & Drug Administration (FDA) and the Center for Medicare and Medicaid Services (CMS), indirectly by Cordis and other stent manufacturers, because the physician and hospital community are undertaking the medically necessary procedures with an "off-label" stent product

[1] In addition to its 1991 vascular stent approval, Cordis also received FDA regulatory approval for the following stents relevant to the allegations in this action: in 1994, PMA approval for the Palmaz-Schatz Balloon Expandable Stent (coronary arteries); in 2003, PMA approval for the S.M.A.R.T. AND S.M.A.R.T. Control Nitinol Stent System (iliac arteries); and, in 2006, PMA approval for the Precise Nitinol Stent System (carotid arteries). These four (4) stents also have 510(k) clearances for use in the biliary tree. Relator's allegations do not acknowledge that Cordis has vascular stents and other products used by hospitals and physicians.

and then submitting "false claims" for payment to Medicare and other federal health care programs.[2]

The publicly-available information, however, powerfully illustrates that the FDA has not been remotely duped by Cordis or any other stent manufacturer and was fully aware that cleared biliary stents (some of which have dual vascular indications) were being used by hospitals and physicians in vascular disease procedures in accordance with FDA and State law practice of medicine requirements; correspondingly, CMS has properly reimbursed hospitals and physicians for these procedures for years with the same knowledge because under Medicare coverage policy such procedures are a reasonable and necessary medical treatment option for patients devastated by peripheral vascular disease.

As the Relator confirms in the Third Amended Complaint, based on FDA's determination that there was a *"reasonable likelihood"* that biliary stents would be used for off-label indications, FDA has, *since 1998*, required that Cordis place the following language on the labeling of its biliary stent devices: *"the safety and effectiveness of this device for use in the vascular system has not been established."* TAC ¶ 12 & 81; *J.D. App.* at 388-390. This determination has been part of Cordis 510(k) biliary stent clearance letters from the FDA no less than 36 times from 1998 to 2010.

Other instances of FDA knowledge are compelling and relevant to this Court's determination of jurisdiction. At a meeting in 2001, for example, the FDA Circulatory Systems Devices Advisory Panel discussion noted the widespread off-label use of stents by physicians without significant safety concern and the impact of physician acceptance of stenting with biliary

[2] A stent is a tiny tube that is placed in a natural passageway or conduit in the body, such as a bile duct or an artery, to prevent or treat an obstruction or flow restriction. Biliary stents are intended to treat obstructions in the bile ducts, which are most commonly caused by pancreatic cancer. Vascular stents are used to treat a narrowing or blockage of arteries or veins caused by conditions such as peripheral arterial disease. www.padcoalition.org

stents on the ability to recruit investigators to conduct randomized clinical trials for new vascular stents. *J.D. App.* at 29, 189-190, 229-230. In 2002, the FDA issued letters to biliary stents manufacturers raising concerns regarding potential off-label use of the stents. *J.D. App.* at 404-407. In 2003, FDA official Dorothy Abel provided an interview to the publication *Endovascular* on off-label biliary stent device use, noting FDA letters issued in 2002 to the biliary stent manufacturers on off-label promotion as well as the legal and clinical authority of physicians to use off-label stents as a treatment option for patients.[3] *J.D. App.* at 335-227 .

The civil fraud action, brought by an employee of another stent manufacturer who has never worked at or been involved in any Cordis business operations, presents a novel but fundamentally deficient False Claims Act legal theory that has been discredited in several recent judicial decisions that have considered whether alleged regulatory violations of the Food Drug & Cosmetic Act (FDCA) may comprise a False Claims Act violation. The procedural history of this action, moreover, presents substantial questions regarding whether the False Claims Act is an appropriate legal vehicle to parasitically launch a private *qui tam* lawsuit against multiple companies in a particular industry for alleged violations of a complex public health regulatory scheme and in the absence of any credible specific information that such companies, *when individually considered*, have actually caused the submission of any false claims to receive payment from the United States treasury.[4]

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[3] The 2003 Abel interview standing alone shows that the allegations in this action are part of public disclosure that occurred years before the original complaint was filed in 2006 and that the Relator is not an original source for any information on the 510(k) clearance process for biliary stents or FDA promotion compliance as it may relate to False Claims Act liability. One disclosure is sufficient to invoke the public disclosure bar.

[4] There is no legal basis for permissive joinder of the parties in this action Fed. R. Civ. P. 20(a); *U.S. ex rel. Health Outcomes Techs. v. Hallmark Health Sys., Inc.*, 409 F. Supp. 2d 43, 47-48 (D. Mass. 2006) (misjoinder where no conspiracy, concert of action, communication, contract, joint or several liability between 100 hospital-defendants alleged); *U.S. ex rel. Grynberg v. Alaskan Pipeline Co.*, 1997 WL 33763820, at *1-2 (D.D.C. 1997) (dismissing 60 of 66 defendants from FCA: "Plaintiff cannot join defendants who simply engaged in similar types of behavior, but who are otherwise unrelated; some allegation of concerted action between defendants is required").

When this action was originally filed in 2006 against several companies, it comprised forty four (44) pages and there was only one specific allegation as to Cordis (Original Complaint at ¶ 33) and no allegations as to Johnson & Johnson. *Docket 1*. These original allegations are the best evidence of the universe of the Relator's knowledge for jurisdictional purposes under the False Claims Act. *See U.S. ex rel. Ortega v. Columbia Healthcare, Inc.*, 240 F. Supp. 2d 8 (D.D.C. 2003); *U.S. ex rel. Ackley v. IBM*, 76 F. Supp. 2d 654, 659-60 (D. Md. 1999) (initial complaint, "the one framed before any possible distortions associated with discovery took place," is highly reliable evidence of Relator's original source status). While the case was pending under seal for several years, successive ex-parte amended and supplemental pleadings were filed until the Relator's complaint allegations and attached exhibits eventually ballooned to a fantastically repetitive level of 215 pages and 494 allegations in the Third Amended Complaint filed in May, 2010. New theories and facts suddenly appeared for the first time in 2010 relating to general anti-kickback violations against "all defendants" that allegedly occurred on or before 2006 when the complaint was originally filed. Notably, now, in 2010, still only 84 allegations of 494 allegations even relate specifically to Cordis and none of these allegations, alone or collectively, reasonably infer any actionable conduct under the False Claims Act.

I. Summary of Cordis' Legal Arguments in Support of Motion to Dismiss|

Cordis denies the allegations in this action. It is clear from an objective review of the record that the FDA has not been misled by Cordis in any regulatory filings and has presumptively exercised appropriate agency discretion to approve and clear biliary stents from 1998 to as recently as 2010 and such stents are lawful for sale and use. FDA also has exercised appropriate agency discretion in determining how best to address its concerns that biliary stents are substantially and lawfully used by the physician community in vascular procedures and to

proactively enhance its oversight of the promotional activities of industry at the same time that CMS has confirmed its coverage of procedures that use biliary stents.

Because materiality is a critical element of any "fraud on the FDA theory", recognizing a viable False Claims Act *qui tam* action for alleged non-compliance with the FDCA 510(k) process and promotional regulations will have the practical effect of eventually requiring a U.S. District Court to pass judgment on federal agency action to determine whether a private citizen may recover funds for himself for alleged regulatory violations that have a non-existent relationship to the submission of a claim of reimbursement from federal health care programs by any hospital or physician. Such an action inherently risks interfering and undermining the FDA's oversight and enforcement role in public health matters.

As False Claims Act *qui tam* actions increasingly sail farther away from the legal moorings of the statute, asserting liability for any type of regulatory violation that can be imagined or cobbled together, there are legitimate and substantial questions of federal court jurisdiction and whether the allegations present any plausible cause of action. Based on a review of the various Complaint allegations and exhibits and the Motion to Dismiss, Declaration and Appendix, applying existing and established judicial precedent, Cordis urges this Court to dismiss this action with prejudice based on the following conclusions of fact and law:

A. The allegations and transactions underlying all of the Relator's complaints, supplements and amendments from 2006 to 2010 are based upon widespread public disclosures in media, administrative hearings, public administrative and federal agency action relating to the off-label use of biliary stents and regulatory concerns of off-label promotion from 1999 to 2010. Joint Defense Appendix and Declaration of Michele Buenafe.

B. The Relator is not an original source as to any of the publicly disclosed allegations of off-label promotion attributable to Cordis. The Relator has not, and cannot, allege

any direct, first-hand and independent knowledge of off-label promotion of biliary stents by Cordis in violation of the False Claims Act. Because the allegations in this action are the subject of widespread public disclosure and because the Relator is not an original source for any actionable conduct related to Cordis, this Court lacks subject matter jurisdiction over this *qui tam* action. *U.S. ex rel. Lam v. Tenet Healthcare Corp*., 287 Fed. Appx. 396, 400-02 (5th Cir. 2008); *see also In re Natural Gas Royalties Qui Tam Litig.,* 562 F.3d 1032, 1046-47 (11th Cir. 2009) (affirming dismissal of 40 out of 73 industry *qui tams* for lack of jurisdiction where relator was not the original source); *U.S. ex rel. Poteet v. Lenke*, 604 F. Supp. 2d 313, 321-22 (D. Mass. 2009) (dismissal of multi-defendant *qui tam* on original source and FRCP (9)(b) grounds). Counts I to XIV should be dismissed on the basis of subject matter jurisdiction.

C. Any presumed violation of the Food Drug and Cosmetic Act (FDCA) promotion regulations does not create a cause of action under the False Claims Act *qui tam* provisions (Count I). Compliance with the FDCA is not a condition of participation or condition of payment under Medicare or other federal health care program and violations of the FDCA are not actionable under the False Claims Act under any recognized express certification or implied certification theories, the latter of which has not even been recognized in this jurisdiction. *U.S. ex rel. Thompson v. Columbia/HCA Healthcare*, 125 F.3d 899 (5th Cir. 1997); *U.S. ex rel. Gonzalez v. Fresenius Med. Care*, 2010 WL 1645971 (W.D. Tex. 2010); *U.S. ex rel. Hutcheson v. Blackstone Med. Inc.,* 694 F. Supp. 2d 48 (D. Mass. 2010); *U.S. ex rel. Stephens v. Tissue Sci. Labs.*, 664 F. Supp. 2d 1310 (N.D. Ga. 2009); *U.S. ex rel. Kennedy v. Aventis Pharma., Inc.,* 2008 WL 5211021 (N.D. Ill. 2008). Count I (Federal False Claims Act) should be dismissed.

D. Count II of the Complaint seeks relief for violations of the federal anti-kickback statute. There is no private cause of action for violation of the federal anti-kickback statute. *Gaalla v. Citizens Med. Ctr.*, 2010 WL 2671705, at *3 (S.D. Tex. 2010). Count II is also

jurisdictionally barred because it was not pled under seal for DOJ's assessment under 31 U.S.C. § 3730(b). Accordingly, Count II must be dismissed in its entirety.

E. The Complaint allegations, though lengthy and conclusory, are inadequate to establish a reasonable inference of actual fraudulent conduct under FRCP 9(b) for any of the Counts of relief asserted. Moreover, allegations of facially legal conduct that do not specify actual false statements or claims under the False Claims Act do not meet the requirements of FRCP 9(b). *U.S. ex rel. Grubbs v. Kanneganti*, 565 F.3d 180 (5th Cir. 2009); *Hopper v. Solvay Pharma., Inc.*, 588 F.3d 1318 (11th Cir. 2009); *U.S. ex rel. Polansky v. Pfizer, Inc.*, 2009 WL 1456582 (E.D.N.Y. 2009); *U.S. ex rel. Radcliffe v. Purdue Pharma L.P.*, 582 F. Supp. 2d 766 (W.D. Va. 2008); *U.S. ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720 (1st Cir. 2007); *U.S. ex rel. West v. Ortho-McNeil Pharma., Inc.*, 2007 WL 2091185 (N.D. Ill. July 23, 2007); *United States ex rel. Franklin v. Parke-Davis*, 2003 WL 22048255 (D. Mass. 2003). Count I through XIV must be dismissed.

F. Johnson & Johnson is not a proper party in this action and has been added gratuitously without any credible effort to plead sufficient allegations under well-recognized legal precedents. Its mere status as a corporate parent to Cordis is insufficient as a matter of law to sustain any action. *In re Pharma. Indus. Average Wholesale Price Litig.,* 538 F. Supp. 2d 367, 391 (D. Mass. 2008) (dismissing J&J in a similar circumstance). Cordis Endovascular is a division of Cordis Corporation. False Claims Act liability may not be asserted against a corporate division. These entities must be dismissed from the action entirely.

G. This Court should decline to exercise jurisdiction over any of the appended State False Claims Act actions (Counts III to XIV). These claims are similarly legally defective for lack of jurisdiction under the respective False Claims Act procedural provisions, failure to state a claim and failure to plead fraud with particularity and should be dismissed.

H. The dismissal of this action should be with prejudice and without leave to further amend**.** *United States ex rel. Hebert v. Dizney*, 295 Fed. Appx. 717, 725 (5th Cir. 2008) (no abuse of discretion in denying relator's request for leave to amend FCA complaint for third time, where proposed amendment did not raise any facts that were not previously available); *U.S. ex rel. Willard v. Humana Health Plan of Tex., Inc.*, 336 F.3d 375, 387 (5th Cir. 2003) ("leave to amend properly denied when further amendment would be futile"); *U.S. ex rel. King v. Alcon Labs., Inc.*, 232 F.R.D. 568, 573 (N.D. Tex. 2005) (denying request to file third amended complaint on futility grounds, noting relator had already amended his complaint on two occasions).

II. Summary of Procedural Background and Regulatory Structure

a. Procedural History and Parties.

This action was initiated in September, 2006 under the private citizen *qui tam* provisions of the False Claims Act. 31 U.S.C. § 3730(b). Relator appends to the federal action several State False Claims Act *qui tam* counts for California, Florida, Illinois, Louisiana, Massachusetts, Tennessee, Texas and Virginia. No specific allegations relevant to these States and Cordis are presented for any assessment, including compliance with the State False Claims Act pre-filing disclosure requirements, and the state law claims should be summarily dismissed.

The Department of Justice (DOJ) commenced a 39-month review of the allegations and in December, 2009 filed a "statement of non-intervention." *Docket 53.* This statement is in effect a declination to intervene and take over the action. 31 U.S.C. § 3730(b)(4). Florida, Tennessee, Illinois, Louisiana, and California filed similar non-intervention statements or declinations. Virginia and Texas filed nothing with the Court and presumably declined to intervene in the action.

In May, 2010 Relator sought and was granted leave to file a Third Amended Complaint (hereinafter TAC) by Order of Magistrate Judge Paul Stickney. *Docket 66.* Johnson & Johnson and Cordis were served with the Third Amended Complaint on or about May 4 and May 10, 2010, respectively. The 2010 Third Amended Complaint was not filed under seal and added new State parties: Delaware, District of Columbia, Michigan, and Minnesota, New Jersey, and New York. By agreement of the parties, with leave of the Court, the agreed date for any responsive pleading to the served Complaint was established as July 16, 2010. *Docket 93 & 98.*

b. False Claims Act Overview Under Fifth Circuit Precedent.

The core statutory structure of the False Claims Act warrants a keen judicial spotlight at the outset because this Court's jurisdiction over a viable *qui tam* action is significantly constrained. As noted by the Court in *U.S. ex rel. Foster v. Bristol-Myers Squibb Co.*, "the focus in an FCA suit must be on the *false claim* itself. As the First Circuit has explained, 'the FCA does not create a cause of action for *all* fraudulent conduct affecting the government.'" 587 F. Supp. 2d 805, 813 (E.D. Tex. 2008) (quoting *U.S. ex rel. Rost v. Pfizer*, 507 F.3d 720, 727 (1st Cir. 2007)) (emphasis in original). "Rather, the fundamental element of an alleged FCA violation is a false or fraudulent claim that is submitted to the government . . . there is no doubt *that the FCA attaches liability not to the underlying fraudulent activity or the government's wrongful payment, but the 'claim for payment.*'" Id. (quoting *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 785 (4th Cir. 1999)) (emphasis added and internal quotations omitted).

Under Count I, Relator asserts False Claims Act liability under 31 U.S.C. § 3729(a) for false claims (a)(1) and false statements (a)(2) against *all* Defendant parties. Section 3729(a)(1) of the False Claims Act ("FCA") states in relevant part:

> Any person who: (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces

> of the United States a false or fraudulent claim for payment or approval; . . . is liable to the United States Government for a civil penalty . . .

The Fifth Circuit applies a four-part test to determine liability under this provision: "(1) whether there was a false statement or fraudulent course of conduct; (2) made or carried out with the requisite scienter; (3) that was material; and (4) that caused the government to pay out money or to forfeit moneys due (i.e., that involved a claim)." *U.S. ex rel. Longhi v. U.S.*, 575 F.3d 458, 467 (5th Cir. 2009) (citations and quotations omitted). In addition to proving that an actual false claim was submitted, relator must demonstrate that the government suffered an injury in fact in order to have standing. *U.S. ex rel. Willard v. Humana Health Plan of Tex., Inc.*, 336 F.3d 375, 386 (5th Cir. 2003). Fifth Circuit precedent recognizes that a false statement is material, if it has a "natural tendency to influence, or is capable of influencing, the decision of the decision-making body to which it was addressed." *Longhi*, 575 F.3d at 468.

Section 3729(a)(2) states in relevant part:

> Any person who: . . . (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government; . . . is liable to the United States Government for a civil penalty . . .

This provision *still requires* the false claim elements outlined above and requires a showing that defendant made or used or caused another to make or use a false record that caused a false claim to be paid. "A plaintiff asserting a § 3729(a)(2) claim must prove that the defendant *intended* that the false record or statement be material to the Government's *decision to pay or approve the false claim.*" *U.S. ex rel. Rafizadeh v. Continental Common, Inc.*, 553 F.3d 869, 874 (5th Cir. 2008) (quoting *Allison Engine Co. v. U.S. ex rel. Sanders*, 533 U.S. 662, 128 S. Ct. 2123, 2126 (2008)) (emphasis added and internal quotation omitted). Relevant to the facts in this case, the Fifth Circuit has also held that false certification of compliance with applicable regulations does <u>not</u> create a basis for liability under the FCA where the payments made were not

expressly conditioned on the allegedly false certifications. *U.S. ex rel. Thompson v. Columbia/HCA Healthcare*, 125 F.3d 899, 902-03 (5th Cir. 1997).

In the context of a declined *qui tam* action, the FCA expressly limits the power of district courts to hear a relator's claims in order to prevent abuse of the *qui tam* provisions. *U.S. ex rel. Stone v. Amwest Sav. Ass'n*, 999 F. Supp. 852, 855 (N.D. Tex. 1997). This statutory protection makes sense because the relator's predominate interest is in a commercial monetary recovery.[5] As noted by other courts, the legislative history of the False Claims Act addresses *qui tam* jurisdiction and the balance to strike in discouraging parasitic or opportunistic suits with the government's interest in learning of unknown fraud. The Ninth Circuit explained the importance of a relator's original source status and reporting unknown fraud to the government in reviewing the FCA's legislative history:

> If . . . someone republishes an allegation that has already has been publicly disclosed, he cannot bring a qui tam suit, even if he had "direct and independent" knowledge of the fraud. He is no "whistleblower." A "whistleblower" sounds the alarm; he does not echo it. The Act rewards those brave enough to speak in the face of 'conspiracy of silence' and not their mimics."

U.S. ex rel. Wang. v. FMC Corp., 975 F.2d 1412, 1419 (9th Cir. 1992) (citing Senate Report at 6, 1986 U.S.C.C.A.N 5271); *see also U.S. ex rel. Trice v. Westinghouse Elec. Corp.*, 2000 WL 34024248, at *6 (E.D. Wash. 2000) (Legislative history of the FCA "makes clear that *qui tam* jurisdiction was meant only to extend to those who had played a part in the public discovery of the allegations and information on which their suits were based.") (citing *U.S. ex rel. Dick v. Long Island Lighting Co.*, 912 F.2d 13, 16 (2d Cir. 1990).

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[5] It is well recognized that declined *qui tams* are not altruistic enterprises. DOJ, CMS and FDA continue to have remedies to exercise in the public interest and the relator's potential monetary recovery will have no impact on the government's exercise of discretion or the continued lawful use of biliary stents by physicians. Parasitic and opportunistic *qui tams* are not entitled to any public interest deference or relaxation of the legal standards for qualifying to bring such actions.

Relevant here, the FCA establishes a bar to jurisdiction in most cases where the allegations in the complaint arise from a public disclosure:

> (4)(A) No court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.
>
> (B) For purposes of this paragraph, "original source" means an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action under this section which is based on the information.

31 U.S.C. § 3730(e)(4).

c. 2009 and 2010 False Claims Act Amendments and Retroactivity.

Since this action was filed in 2006, the False Claims Act has been amended twice, in 2009 and 2010, respectively, and the issue of retroactivity is a question to be briefly considered in this action.[6] The 2009 amendments codified the judicially recognized materiality standard among other changes not directly relevant to this action. To date, the Fifth Circuit has not addressed whether the 2009 False Claims Act amendments in the Fraud Enforcement and Recovery Act of 2009 (FERA) apply retroactively. *Longhi*, 575 F.3d at 470. Recent cases, however, have generally rejected or limited the retroactive effect of the 2009 amendments. *U.S. ex rel. Sanders v. Allison Engine Co., Inc.,* 667 F. Supp. 2d 747, 752 (S.D. Ohio 2009) (retroactivity provision only applies to "claims" pending—not cases—as of June 7, 2008 and noted that a claim is defined as a "request or demand . . . for money or property" under the FCA); *see also U.S. v. Sci. Applications Int'l Corp.*, 653 F. Supp. 2d 87, 107 (D.D.C. 2009) (limiting application of FERA's retroactivity provision to "claims," not cases); *U.S. v. Aquillon,*

[6] The 2009 amendments changed the statute for citation purposes as well, re-lettering certain provisions under 31 U.S.C. § 3729, among other things. For purposes of this brief, Cordis has cited to the pre-2009 version of the statute.

628 F. Supp. 2d 542, 550-51 (D. Del. 2009). *But see U.S. ex rel. Carter v. Halliburton Co.,* 2009 WL 2240331, at *5 n.3 (E.D. Va. 2009) (claims allowed when pending on effective date); *U.S. ex rel. Walner v. Northshore Univ. Healthsystem*, 660 F. Supp. 2d 891, 896 n.3 (N.D. Ill. 2010) (applies three-part test to claims pending at the time of amendment). The 2010 False Claims Act amendments passed by the Patient Protection and Affordable Care Act (PPACA) (Pub. L. No. 111-148) revise the original source exception to the public disclosure bar but these provisions are not retroactive. *See Graham County Soil & Water Conservation Dist. v. U.S. ex rel. Wilson*, 130 S. Ct. 1396, 1400 n.1 (2010).[7]

d. Federal Anti-Kickback Statute.

The federal Anti-Kickback Statute makes a last-minute appearance in this action as a stand alone count for relief (Count II) with a new litany of vaguely described so-called inducements that "all Defendants" allegedly provided to doctors and hospitals to insure the use of their biliary stents. The anti-kickback statute, generally, prohibits the paying or offering of "remuneration" to *induce* the purchasing or recommending of "any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. § 1320a-7b(b). The statute contains statutory exceptions and regulatory safe harbors that authorize a host of professional and business transactions and interactions. *See, e.g.,* 42 C.F.R. § 1001.952, *et seq.* Discounts and other price concessions, for example, are expressly authorized under the anti-kickback statute as an exception, 42 U.S.C. § 1320a-7b(b)(3)(A), and there is an applicable safe harbor, 42 C.F.R. § 1001.952(h). Similarly, personal services

[7] 31 U.S.C. 3130(e)(4)(A) now provides: "'original source' means an individual who either (i) prior to a public disclosure under subsention (e)(4)(a) has voluntarily disclosed to the government the information on allegations or transactions in a claim are based, or (2) who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under this section." Relator does not qualify as an original source under this standard.

agreements for physician teaching, training and consulting are also authorized. 42 C.F.R. § 1001.952(d).

It is axiomatic that the anti-kickback statute provides for no private cause of action. *Gaalla v. Citizens Med. Ctr.,* 2010 WL 2671705, at *3 (S.D. Tex. 2010). Absent an express certification of compliance with the anti-kickback statute by the party seeking reimbursement as a condition of payment that is materially false, moreover, no False Claims Act action may be recognized. Such certification must be material to payment. *U.S. ex rel. Kennedy v. Aventis Pharma., Inc.*, 2008 WL 5211021 *5-6 (N.D. Ill. 2008) (failure to tie hospital cost reports to particular false claims fails to show cost reports are material to payment of claim). The certification of compliance applies only to the party seeking reimbursement, *i.e.* the hospital or physician. The certification of compliance is limited and does not encompass any certification or representation by a third-party or related to third-party conduct. *U.S. ex rel. Hutcheson v. Blackstone Med., Inc.*, 694 F. Supp. 2d 48, 62-63 (D. Mass. 2010) (in *qui tam* action finding that hospital certifications as a matter of law cannot be false based on anti-kickback violations by device company where certification statement is specific to individual and does not certify the entire transaction complied with the anti-kickback statute and creates no obligation on certifier to make such a determination); *see also U.S. ex rel. Conner v. Salina Reg'l Health Ctr.,* 543 F.3d 1211 (10th Cir. 2008) (in *qui tam* action rejecting cost report broad certification of compliance with all laws as actionable under the FCA for regulatory violations *en masse*); Cf. *U.S. ex rel. Schmidt v. Zimmer, Inc.,* 386 F.3d 235, 243 (3d Cir. 2004).

e. Material FDA and Medicare Program Requirements.

Cordis disputes the regulatory description of the FDA and Medicare program regulations contained in the Third Amended Complaint, which is rife with inaccuracies and omissions and fundamentally unreliable. This Court need not resolve, however, any dueling regulatory

perspectives to consider the arguments presented in the respective motions to dismiss and opposition pleadings filed by the parties in this action. There is a simple truth to discern in the storm of arguments involving False Claims Act actions premised on violations of FDA promotion regulations.[8] Compliance with FDA promotion regulations is not related to Medicare coverage regulations at all and this Court is not required to make any underlying reimbursement coverage determinations to conclude that physicians and hospitals do not have to expressly certify compliance with FDA promotion regulations to obtain payment from federal health care programs. The two distinct statutory schemes are unrelated for False Claims Act purposes, notwithstanding the presumption to the contrary in some judicial decisions and by advocates.

Because compliance with any aspect of the FDCA is not an express condition of payment there can be no False Claims Act violation for the fraud on the FDA theory asserted (510(k) process) or for the submission of a materially false *claim* by hospitals or physicians that use a biliary stent in any vascular procedure. With no false claim, there can be no False Claims Act violation for causing the submission of a false claim or making a false statement to get a false claim paid. *U.S. ex rel. Thompson, supra*, 125 F.2d at 902; *U.S. ex rel. Mikes v. Strauss,* 274 F.2d 687, 698-699 (2d. Cir. 2001). The Court should not accept the Relator's invitation to engage in unnecessary and broad regulatory determinations. The False Claims Act "*attaches liability not*

[8] The reference to FDA promotional regulations itself is a bit of a misnomer as there is no precise regulation and much of the understanding comes from FDA agency guidance documents that are not codified. For the relevant time period of this action, FDA policy permitted the dissemination of scientific and clinical information related to unapproved uses in response to requests from health care providers. *See* 59 Fed. Reg. 59820, 59823 (Nov. 18, 1994) ("Under current FDA policy, companies may also disseminate information on unapproved uses in response to unsolicited requests for scientific information…") (codified under Section 401 of the Food and Drug Modernization Act of 1997 at Section 557(a) of the FCDA, 21 U.S.C. § 360aaa-6, which sunset on September 30, 2006). There is no misunderstanding that products may only be promoted for an approved intended use. There is a gallactical void, however, in legally defining and assessing the concepts of promotion versus authorized dissemination of information. Such a void is not appropriate for resolution under the important statutory purposes served by the False Claims Act.

to the underlying fraudulent activity or the government's wrongful payment, but the 'claim for payment." Foster, 587 F. Supp. 2d at 813.

To avoid excessively duplicative effort for the Court's review, Cordis otherwise adopts and incorporates by reference the regulatory background and arguments provided in the Motion to Dismiss pleadings filed, respectively, by Defendants Boston Scientific and Abbott Laboratories. Cordis highlights the following material issues for the Court's consideration.

1. Biliary stents are not investigational or experimental devices under the FDA or CMS regulatory schemes. 21 U.S.C. § 360(k). Such stents have been cleared or approved by FDA for marketing in the United States and may be lawfully used by physicians *in procedures* that are funded by federal health care payors.[9] It is undisputed in this action that physicians have complied with the practice of medicine doctrine recognized in the FDCA and used biliary stents within legitimate physician-patient relationships in medically necessary vascular procedures.[10] TAC ¶ 14.

2. CMS, the Medicare and Medicaid federal agency, does not prohibit reimbursement for vascular procedures that may involve the use of a biliary stent. In fact, it does not presumptively ban reimbursement generally for procedures that may use an off-label product. *See, e.g., U.S. ex rel. Stephens v. Tissue Sci. Labs.,* 664 F. Supp. 2d 1310, 1318 (N.D. Ga. 2009)

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[9] *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 350 (2001); *see also* Food & Drug Admin., *Guidance for Industry: Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices* (Jan. 2009) http://www.fda.gov/RegulatoryInformation/Guidances/ucm125126.htm (last visited on July 15, 2010) ("Once a drug or medical device has been approved or cleared by FDA, generally, healthcare professionals may lawfully use or prescribe that product for uses or treatment regimens that are not included in the product's approved labeling (or, in the case of a medical device cleared under the 510(k) process, in the product's statement of intended uses).").

[10] *See* 21 U.S.C. § 396; *see also Legal Status of Approved Labeling for Prescription Drugs; Prescribing for Uses Unapproved by the Food and Drug Administration*, 37 Fed. Reg. 16503, 16503 (proposed Aug. 15, 1972) ("…Congress did not intend the Food and Drug Administration to interfere or regulate the practice of medicine as between the physician and the patient.").

(declining to recognize FCA liability for off-label or experimental use of device on basis such is immaterial in hospital reimbursement).[11] Rather, CMS focuses on what is reasonable and necessary for the patient as determined by the physician and informed by peer review medical literature support. *Medicare Program Integrity Manual* § 13.5.1, 60 Fed. Reg. 48417, 48417-20 (September 19, 1995); *see also* National Coverage Decision Manual, Chapter 1, Part 1, § 20.1; Steve Phurrough, Director, Coverage & Analysis Group, CMS, *Coverage Decision Memorandum for Percutaneous Transluminal Angioplasty (PTA) and Stenting of the Renal Arteries* (CAG-00085R4) (Feb. 14, 2008), *J.D. App.* at 827-860 (affirming Medicare coverage for renal stent procedures despite fact "there are presently no FDA approved devices for primary stenting or distal embolic protection in the renal arteries" and with knowledge that "virtually all of the renal stenting procedures currently conducted in the U.S. are performed using *stents not indicated for use in the renal vasculature, most commonly including biliary stents*").[12]

3. Physicians and hospitals do not submit claims for payment for biliary or vascular stents. They submit claims *for procedures and are reimbursed for services and procedures* without regard to which stent the physician determines to use in the best interest of the patient. *Hutcheson*, 694 F. Supp. 2d at 62-63.

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[11] The Court decision cites expressly to the Federal Register Preamble for DRG regulations, 48 Fed. Reg. 39752, 39787 (Sept. 1, 1983) ("It should be noted in this regard that only if the *sole or primary* services (beyond routine care) provided to a patient are noncovered will the admission (and therefore prospective payment) be denied. This means that as long as an acceptable or proven diagnostic or treatment course (for the DRG) is present, even if noncovered care is also present, the payment will be made."). *See* 664 F. Supp. 2d at 1318.

[12] Medicare contractors have also issued local coverage determinations supporting coverage. TriSpan Health Serv., *LCD for Outpatient Transcather Placement of Non-Coronary Artery Stents* (L1523) (effective June 24, 2002; rev. Mar. 8, 2005), *J.D. App.* at 875-885; Palmetto GBA, *LCD for Non-Coronary Vascular Stents* (L6944) (effective Nov. 1, 2000; rev. Oct. 1, 2008), *J.D. App.* at 886-897; Pinnacle Bus. Solutions, Inc., *LCD for Non-Coronary Vascular Stents* (L16150) (effective Apr. 15, 2004; rev. Nov. 1, 2004), *J.D. App.* at 898-905. These coverage decisions do not prohibit the use of a biliary stent in a vascular procedure or render such procedure ineligible for coverage if a physician determines to use a biliary stent in the procedure.

III. Relator's Action Is Barred Under False Claims Act Public Disclosure Bar.

a. Jurisdictional Standard of Review.

The False Claims Act establishes subject matter jurisdiction for both private citizen *qui tam* actions and the underlying cause of action. The jurisdictional inquiry under FRCP 12(b)(1) is necessarily intertwined with the merits of the allegations. Accordingly, it is appropriate for the Court to view the FRCP 12(b)(1) motion as a motion for summary judgment under FRCP 56(c) and consider materials and exhibits to determine subject matter jurisdiction. *U.S. ex rel. Laird v. Lockheed Martin Eng'g & Sci. Servs. Co.,* 336 F.3d 346, 350 (5th Cir. 2003) *abrogated on other grounds by Rockwell Int'l Corp. v. U.S.,* 549 U.S. 457 (2007). As this Court has noted, any doubts as to subject-matter jurisdiction must be resolved at the outset of an action, even before ruling on other grounds for dismissal. *U.S. ex rel. Barrett v. Johnson Controls,* 2003 WL 21500400, at *3 (N.D. Tex. 2003).

In this motion, Cordis presents both a facial and factual attack on subject matter jurisdiction. Notably, the Relator pleads facts and circumstances in the Third Amended Complaint that defeat the Court's jurisdiction by establishing the public disclosure of the underlying basis of the action. *See, e.g.,* TAC ¶ 3 (over decade of off-label promotion by defendants and over 95% usage of biliary stents in vasculature); ¶ 12 (FDA-imposed warning on labels that safety and effectiveness of biliary stents not approved for vascular use); ¶ 17 (virtually all stents implanted to treat vascular disease off-label); ¶ 21 (Cordis' May 2004 nationwide recall of Precise RX biliary stent); ¶ 74 (FDA Office of Device Evaluation FY 2006-07 Annual Report noting FDA's concerns about off-label promotion of biliary stents "over the past several years" and FDA required labeling "since 1999" driven by "FDA's concerns regarding off-label use"); ¶ 79 & 81 (FDA clearance letters for each device noting likelihood of off-label use and requiring label warning regarding safety and effectiveness). These allegations are sufficient to establish

public disclosure prior to September, 2006, the original filing of the action, up to May 2010, when the Third Amended Complaint was filed. Cordis further relies on the Joint Defense Appendix affirming publicly available material for which judicial notice is authorized to further establish public disclosure and that the Relator is not the original source of any allegations against Cordis.

b. Summary of Undisputed Material Facts Related to Public Disclosure.

Relator alleges: *"There was no public disclosure of the allegations or transactions set forth in this action prior to filing under 31 U.S.C. § 3730(e)."* TAC ¶ 31. This allegation, frankly, strains all credulity as a review of the voluminous public disclosures *prior to 2006* makes quite obvious. As illustrated in the Joint Defense Appendix filed on behalf of all Defendant parties, since 1999 there has been wide spread public information regarding the off-label use of Cordis biliary stents in vascular procedures and the FDA's concerns over potential off-label marketing by stent manufacturers published in a variety of different publicly available sources—FDA announcements and other materials, Cordis product recall documents, conventional media articles, and industry scientific and medical literature—all of which predate Relator's September 2006 Complaint and subsequent amendments.[13]

These materials establish as to Cordis and the other stent manufacturers that the allegations in the various complaints filed in this action are based upon and substantially related to the public disclosures and that any information in the possession of the Relator prior to the filing of this action is not legally consequential to confer jurisdiction on this Court. Below are

[13] There exist several medical and scientific journals on the off-label use of biliary stents that constitute public disclosure under the statute. *J.D. App.* at 254-256, 257-284, 285-289, 295-313, and 319-334. These disclosures are cumulative to the federal administrative hearings, news media and public agency action and are further detailed in the Joint Defense Appendix. *See Radcliffe*, 582 F. Supp. 2d at 770; *U.S. ex rel. Alcohol Found., Inc. v. Kalmanovitz Charitable Found., Inc.*, 186 F. Supp. 2d 458, 463 (S.D.N.Y. 2002) (scholarly scientific and technical publications qualify as news media under FCA statutory provisions on pubic disclosure).

selected disclosures relevant to the time period prior to 2006 that illustrate this action is jurisdictionally barred. The Joint Defense Appendix contains additional disclosures from the time period 1999 to 2008 that show the widespread disclosures relevant to any amended complaints.

Administrative Hearing Materials

J.D. App.	Date	Title
013-243	Apr. 2001	Transcript of the Circulatory System Devices Advisory Panel Meeting, Open Session, April 23, 2001, *available at* http://www.fda.gov/ohrms/dockets/ac/01/transcripts/3747t1.rtf. Reporting the "rampant off-label use of stents" for iliac and other vascular uses.

Media Documents

J.D. App.	Date	Title
290	May 1999	*J&J's S.M.A.R.T. Stent Journal Ad Implies Off-label Use - FDA Says*, The Gray Sheet, May 17, 1999, at 9, *available at* http://thegraysheet.elsevierbi.com. Reporting the April 1999 Warning Letter from FDA to Cordis concerning its advertisement for the S.M.A.R.T. stent.
291-292	June 1999	*FDA Off-label Use Concerns Focus on Biliary Stents, Mapping Catheters*, The Gray Sheet, June 7, 1999, at 6, *available at* http://thegraysheet.elsevierbi.com. Reporting six cases in which FDA determined that there is a "reasonable likelihood" that biliary stents would be used for an off-label use that could cause harm, and required the stent labeling to include a warning against vascular use. The article also discusses the April 1999 Warning Letter from FDA to Cordis concerning its advertisement for the S.M.A.R.T. stent.
293-294	Aug. 1999	*Off-label Dissemination Still Must Disclose Interest, Unapproved Status*, The Gray Sheet, Aug. 2, 1999, at 4, *available at* http://thegraysheet.elsevierbi.com. Reporting FDA's concerns related to the off-label use of biliary stents.
335-337	2003	D.B. Abel, *Off-label Medical Device Use*, 2(2) Endovascular Today 60-61 (2003), *available at* http://www.evtoday.com/FDA%20Articles/March2003.html. Written by a Regulatory Review Scientist with FDA's Center for Devices and Radiological Health, this article reports the large number of biliary stents recently cleared for marketing and FDA's concerns related to the off-label use of such stents for vascular indications.

338	May 2004	*Cordis Announces Nationwide Recall of Revised Stent Instructions*, Pharmaceutical Processing, May 10, 2004, at 1, *available at* http://www.pharmpro.com/Archives/2004/05/Cordis-Announces-Nationwide-Recall-of-Revised-Stent-Instructions/. Reporting the Cordis May 2004 recall of its instruction sheets for the Precise RX Nitinol Stent Transhepatic Biliary System due to patient injuries that occurred when the stent was used off-label in the vascular system. Cordis publicly stated that it regretted that its "initial communication did not more strongly reinforce against off-label use."
339	July 2004	*Warning on Using Cordis Biliary Stent in the Vascular System*, Medical News Today, July 11, 2004, at 1, *available at* http://www.medicalnewstoday.com/articles/10572.php. Reporting a warning issued by Cordis to health care professionals related to the off-label use of the Precise RX Nitinol Stent Transhepatic Biliary System in the vascular system.
340-358	Spring 2006	S. Portnoy, *Advertising and Promotion of Medical Devices*, J. Health Law, Spring 2006 Vol. 39, No. 2, at 277-278, *available at* http://www.lexisnexis.com/. Reporting "[a] Warning Letter dated April 28, 1999 to Cordis Corporation [which] addressed the issue of different intended use."
362-363	Oct. 2006	*FDA Official Scolds Industry for Supporting Off-Label Use of Biliary Stents*, The Gray Sheet, Oct. 30, 2006, *available at* http://thegraysheet.elsevierbi.com. Reporting statements by Donna-Bea Tillman, director of FDA's Office of Device Evaluation, concerning the device industry's support for the off-label use of biliary stents in femoral arteries.

Public Agency Documents

J.D. App.	Date	Title
388-390	Dec. 1998	Section 510(k) Premarket Notification Clearance Letter for K980823 from FDA, CDRH to Cordis Corporation (Dec. 18, 1998), *available at* http://www.accessdata.fda.gov/cdrh_docs/pdf/K980823.pdf. This Clearance Letter states that "[t]he Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm." Thus, FDA required the following warning to appear on the device labeling: "The safety and effectiveness of this device for use in the vascular system have not been established."
391-393	Apr. 1999	Warning Letter from Office of Compliance, CDRH, FDA to Cordis Corporation (Apr. 28, 1999), *available at* http://www.fda.gov/downloads/ICECI/EnforcementActions/WarningLetters/1999/UCM067310.pdfhttp://www.accessdata.fda.gov/cdrh_docs/pdf/K980823.pdf. This letter warns Cordis that its advertisement for the S.M.A.R.T. stent make "an implied claim for vascular use for the stent" when the stent had only been cleared for use in the biliary tree.
408	May 2004	FDA, Biliary Stents Instructions for Use, Class I Recall, May 4, 2004, *available at* http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/ucm064818.htm. This FDA notice describes the Cordis Class I recall of its revised instructions for use for the Precise RX stent due to patient injuries that occurred when the stent was used off-label for vascular use.

409	May 2004	FDA Safety Alert, Precise Rx Nitinol Stent Transhepatic Biliary Stent System (May 2004), *available at* http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm155674.htm. This alert describes the Cordis Class I recall of its revised instructions for use for the Precise RX stent due to patient injuries that occurred when the stent was used off-label for vascular use.
410-417	2006-2007	Office of Device Evaluation Annual Report, Fiscal Year 2006 and Fiscal Year 2007, at 26-27, *available at* http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/ucm127516.pdf. Stating that FDA (1) had been investigating the off-label use of biliary stents for "several years", (2) had been tracking increased Medical Device Reports for off-label biliary use for the past "five years," and (3) had at some earlier time established an action team to address "off-label promotion of biliary stents."

c. False Claims Act Public Disclosure Bar.

The Fifth Circuit has adopted a three-part inquiry to analyze whether subject matter jurisdiction is precluded by the public disclosure bar: "1) whether there has been a 'public disclosure' of the allegations or transactions; 2) whether the *qui tam* action is 'based upon' such publicly disclosed allegations; and 3) if so, whether the Relator is the 'original source' of the information." *Fed. Recovery Servs., Inc. v. U.S.*, 72 F.3d 447, 450 (5th Cir. 1995). Relator's allegations against Cordis are based upon public disclosures made by the FDA, the news media, and Cordis itself that are available in the public domain. Relator has no direct or independent knowledge of any Cordis actions and he is not an original source of any actionable information involving Cordis.

Under the FCA public disclosure bar, information constitutes "allegations or transactions" if it reveals the allegation of fraud, the elements of the underlying fraudulent transaction, or if it allows one to draw an inference of fraud. *Johnson Controls*, 2003 WL 21500400 at *6. The first element of Relator's fraud allegation against Cordis is that Cordis filed pre-market clearance notifications with the FDA certifying that the stents at issue were intended for use in the biliary tree when in fact Cordis intended to market the biliary stents for

use in the peripheral vasculature. TAC ¶¶ 2, 4A-4B, 72, 77-82 & 212-72. Second, Relator alleges that Cordis solicited off-label use of the biliary stents in the vascular system. TAC ¶¶ 4C, 13-13AA & 116-80. These allegations are the cornerstone of Relator's claims against Cordis as they describe the purported "fraud."

As Relator's allegations in the Third Amended Complaint concede, information relating to the FDA's awareness of potential use beyond the approved label was identified in 1998; moreover, information suggesting and even directly stating that Cordis has allegedly engaged in off-label promotion of its biliary stents has been publicly disclosed since at least 1999. *See* TAC ¶ 74 (FDA required labeling "since 1999" per "FDA's concerns regarding off-label use"). Thus, taking as true Relator's fundamental allegations that Cordis engaged in off-label promotion of its biliary stents for use in the vasculature, such allegations were publicly disclosed both in administrative reports and in the news media well before the Relator filed his original complaint. Moreover, all of the allegations and transactions were available in the public domain. *See Johnson Controls*, 2003 WL 21500400, at *5 (treating as publicly disclosed all allegations and transactions that are in the public domain whether or not they have been widely disseminated).

Relator's *qui tam* action against Cordis is "based upon" the foregoing public disclosure of the allegations or transactions. In the context of subject matter jurisdiction under the FCA, "based upon" means "supported by" and "this element is met where a substantial identity exists between the relator's allegation and the public disclosure." *U.S. ex rel. Richardson v. E-Systems, Inc.,* 1999 WL 324666, at *3 (N.D. Tex. 1999). As explained above, Relator's allegation that Cordis actively promoted off-label use of it biliary stents in the vasculature is identical to the publicly disclosed information.

The Relator's original and successive amended complaints present only a "re-animation" of widespread pubic disclosures. New transactions or details that are substantively the same as

those previously disclosed are deemed publicly disclosed as well. *U.S. ex rel. Lujan v. Hughes Aircraft Co.*, 162 F.3d 1027, 1032-33 (9th Cir. 1998); *see also U.S. ex rel. Rosales v. San Francisco Housing Auth.*, 173 F. Supp. 2d 987, 997 (N.D. Cal. 2001) (publicly disclosed allegations cannot be "re-animated" simply by complaining of the same fraudulent actions in successive years even if the details may differ). Finally, it is obvious that the core allegations are redundant, cumulative and derivative to the publicly disclosed allegations. Here, the public information attributable to Cordis and other stent manufacturers is the same as the core operative facts of the complaint allegations. Accordingly, there is a substantial identity between the public disclosures and the allegations and the disclosure bar applies. *U.S. ex rel. Fried v. West Ind. Sch. Dist.*, 527 F.3d 439, 442-43 (5th Cir. 2008); *Kennedy*, 512 F. Supp. 2d at 1166.[14]

d. The Relator Is Not An Original Source.

Because Relator's claims against Cordis are based upon publicly disclosed information, this action can only survive if he is an "original source" of the information. *Fed. Recovery Servs*., 72 F.3d at 450. To qualify as an original source, "[t]he Relator must have direct and independent knowledge of the information on which the allegations are based, and he must provide the information to the Government before filing an action under this section which is based on the information." *Rockwell Int'l Corp. v. U.S.*, 549 U.S. 457, 471 (2007). Further, the Relator must be the original source of *every* claim he brings. *Id*. at 476 ("Section 3730(e)(4) does not permit jurisdiction in gross or claims smuggling just because a relator is an original

[14] Relator's strategy to assert industry-wide allegations is unavailing. Industry wide public disclosures bar *qui tam* actions against any defendant who is directly identifiable from the public disclosures. *In re Natural Gas Royalties Qui Tam Litig.*, 467 F. Supp. 2d 1117, 1147-48 (D. Wyo. 2006); *see also Gear v. Emergency Medicine Med. Ass'n of Ill.*, 436 F.3d 726, 729 (7th Cir. 2006). Virtually all of the public disclosures directly reference Cordis and its biliary stents.

source with respect to some claim.") Thus, Relator must have direct and independent knowledge of all claims he makes, not just claims against certain defendants.

Direct and independent knowledge generally means knowledge that is first-hand and obtained from the relator through his/her own efforts; significantly, a relator's efforts at confirming or accumulating additional information of the same substantive information that is already publicly disclose does not confer original source status as to companies for which relator was not directly employed. *Lam*, 287 Fed. Appx. 396; *In re Pharma. Indus. Average Wholesale Price Litig. v. Ortho-McNeil Pharma.,* 538 F. Supp. 2d 367, 389 (D. Mass. 2008) (relator may be original source as to employer but not as to others in industry wide allegations). Knowledge is independent only if it is based on information that is not publicly disclosed. *Laird*, 336 F.3d at 352-353.

Relator pleads that he has "direct and independent knowledge" of the information on which the allegations are based through previous marketing positions—with a defendant other than Cordis—where he became aware of "the pervasive off-label marketing and promotion set forth herein." TAC ¶ 22. A comparison of the public disclosure chronology and the Relator's claim of independent knowledge cannot be credibly reconciled. At best, Relator's alleged direct and independent knowledge is additive and cumulative and acquired well after the public disclosures occurred.

The Relator does not plead, moreover, a basis for any "direct" or "independent" knowledge regarding Cordis. Instead, Relator relies on a few vague allegations in which he states that he "witnessed" Cordis employees engage in off-label promotion of biliary stents—with no further detail or elaboration—and that he "confirmed" his suspicions regarding off-label promotion through an alleged conversation with a Cordis employee. TAC ¶¶ 141, 142, 148, 159 & 160. The alleged conversation does not indicate any such direct and independent

knowledge.[15] "[W]hen a Relator's claim is based on knowledge received from other persons it is not direct and independent." *Lam*, 287 Fed. Appx. at 401-02.

All other allegations in the Third Amended Complaint are based on Relator's alleged experience in the employ of another defendant. Employees without specific and relevant personal observations and knowledge cannot qualify as an original source, *see, Rockwell, supra,* 127 S.Ct. at 1409-1410; here, the allegations against Cordis are from a non-employee with no first hand knowledge who is observing action from a distance and summarily concluding illegal activity has occurred-from using a PDA to scan inventory or from being present during a vascular procedure. The concept of original source requires much more to confer jurisdiction. *U.S. ex rel. Lam v. Tenet Healthcare Corp.*, 2008 WL 2835215 at *4-5 (5th Cir. 2008) (noting distinctions in opportunity for first hand knowledge and information acquired from others). It is insufficient to take what may be direct or independent knowledge about one party and extrapolate it to cover all parties in a case. *See Branch Consultants, L.L.C. v. Allstate Ins. Co.*, 668 F. Supp. 2d 780, 798 (E.D. La. 2009) (determining that Relator was not an original source where the complaint sought "to extrapolate from plaintiff's experience" with one defendant to broader allegations against other defendants in the industry).

In re Natural Gas Royalties Qui Tam Litig. illustrates an important perspective when relator's claim to have a modicum of knowledge about publicly-disclosed allegations or transactions. In response to an industry-wide *qui tam* with very little direct information about specific defendants, the Court in *Natural Gas* established a "substantiality" standard to apply in such situations to weigh a relator's alleged independently discovered information against the

[15] Relator also alleges one other conversation with a Cordis employee in which the Cordis employee purportedly stated that Cordis trained sales representatives in a vasculature laboratory. TAC ¶ 124. Taking this statement as true, it does not amount to direct knowledge in support of Relator's claims against Cordis as Cordis has PMA-approved stents for use in the vasculature. Even if this allegation had relevance to Relator's claims, it too is based on knowledge received from another person.

entirety of the allegations on which he based his claim–finding subject matter jurisdiction only if his contribution in terms of direct and independent knowledge was, in fact, substantial. 562 F.3d 1037, 1046. The Court determined that the Relator's independent and direct knowledge with regard to each of the defendants was "minimal in comparison to the broad scope of his allegations against them." *Id*.

Accordingly, even if this Court credits the Relator's non-specific allegation that he "witnessed" Cordis employees engage in "off-label promotion" via facially lawful conduct as faintly suggesting a very limited amount of direct and independent knowledge, the substantiality test compels the conclusion that Relator's alleged independently discovered information regarding Cordis does not convey an original source status to credibly sustain jurisdiction. The overwhelming majority of Relator's allegations against Cordis are extrapolated from his alleged experience with another defendant. Relator then pleads his voluminous suspicions about Cordis on essentially one direct basis of independent knowledge: "I saw Cordis do it too." One direct allegation—without any detail—cannot create original source status as to countless broader allegations that are part of widespread public disclosures that have occurred from 1998 to 2010.

e. Alternative Request for Jurisdictional Discovery.

The Third Amended Complaint, however, should not even be considered the sole operative document to determine Relator's status as an original source. In order to be considered an original source, the Relator must not only have direct and independent knowledge of the allegations, but he must also voluntarily disclose that information to the Government *prior* to filing a complaint. *Reagan v. E. Tex. Med. Ctr. Reg'l Healthcare Sys.*, 384 F.3d 168, 175, 177 (5th Cir. 2004); *In re Natural Gas Royalties*, 562 F.3d at 1044 (10th Cir. 2009) ("assessment of Relator's knowledge in this case is limited to information he voluntarily provided to the government before filing suit.") .

If the Court determines that Relator presents a credible question as to whether he is an original source of the allegations against Cordis, Cordis requests leave to conduct limited discovery into the sufficiency of Relator's pre-filing voluntary disclosures and written disclosure statements, and to take the deposition of Relator as to the information regarding each defendant he presented to the government prior to the filing of the original complaint. *U.S. ex rel. Ward v. Commercial Metals Co.*, 2007 WL 1390612, at *1-2 (S.D. Tex. 2007) (carrying forward defendant's motion to dismiss for 45 days to allow parties to conduct limited discovery on the issue of subject matter jurisdiction). Relator's Third Amended Complaint present new facts and counts, *i.e.*, alleged anti-kickback violations, that were not substantively presented to the government at or before the time this action was filed in September, 2006 or presumptively in any amendments. These allegations cannot be jurisdictionally boot-strapped into the original allegations to circumvent compliance with the *qui tam* pre-filing disclosure provisions.

IV. The Complaint Fails to Meet the Requirements of FRCP 12(b)(6) and 9(b).

The Relator's allegations, taken as true, establish no plausible cause of action under FRCP 12(b)(6) or FRCP 9(b) for violations of the False Claims Act. The generalized industry allegations against "All Defendants" should be rejected against any particular company and such pleading tactics should be strongly discouraged. This action does not assert conspiracy or other concerted actions by the stent manufacturer companies; accordingly, the so-called industry allegations are not amenable to "group assessment" by the Court. *Johnson Controls*, 2003 WL 21500400, at *13 n.88 ("Allegations that lump all defendants together, failing to segregate the alleged wrongdoing of one from those of another do not satisfy the requirements of 9(b).") (citing *U.S. ex rel. Stewart v. La. Clinic*, 2002 WL 1066745, at *2 (E.D. La. 2002)) (internal citations omitted).

Focusing on the small subset of allegations specific to Cordis does not reveal any actionable conduct or even facts that support a regulatory violation. As one court has noted, facially legal conduct cannot be inferred to be illegal to support a False Claims Act action. *U.S. ex rel. Laucirica v. Stryker Corp.*, 2010 WL 1798321, at *5 (W.D. Mich. 2010). Further, to the extent Relator offers legal conclusions that any conduct comprised "off-label promotion", such conduct is part of widespread public disclosure prior to 2006 and is not actionable. In wading through the lengthy and repetitive complaint pages it appears that the Relator specifically alleges as to Cordis that:

> (1) he "confirmed" with Brian Abe (Cordis sales representative) that Cordis trained its sales representatives in a vascular laboratory on how to read vascular angiograms and allowed them to watch live peripheral vascular cases. TAC ¶ 124. This conduct is facially lawful.
>
> (2) he "observed" Brian Abe solicit off-label use of Cordis stents. TAC ¶ 141. This allegation is a conclusion without legally sufficient detail.
>
> (3) an unnamed Cordis representative offered a hospital substantial contractual discounts off the list price for their biliary stents if the hospital agreed to stock their biliary stents in the catheterization lab for vascular use. TAC ¶ 142. This conduct is facially lawful.
>
> (4) he "witnessed" Brian Abe attend live vascular stenting procedures and successfully promote Cordis stents for off-label use to two doctors. TAC ¶ 142. This conduct is facially lawful in part and conclusory without legally sufficient detail in part.
>
> (5) he "confirmed" with Holt Parke (Cordis sales representative) that he had only seen a biliary stent used in the biliary tree a few times in his career. TAC ¶ 148. This conduct is facially lawful.
>
> (6) he "witnessed" Mr. Parke attend vascular procedures where he successfully promoted Cordis biliary stents for off-label purposes. TAC ¶ 148. This conduct is facially lawful in part and conclusory without legally sufficient detail in part.
>
> (7) he "witnessed" Mr. Parke stock Cordis biliary systems on consignment in the catheterization lab and surgery department of a hospital. TAC ¶ 148. This conduct is facially lawful.

(8) he "witnessed" Mr. Parke use a Cordis scanner to inventory devices in departments that did not perform biliary procedures. TAC ¶ 159. This conduct is facially lawful.

(9) he "witnessed" an unnamed Cordis representative consign biliary stents for vascular use to three hospitals. TAC ¶ 160. This conduct is facially lawful.

(10) he attended a meeting where Nick Valeriani (allegedly "Worldwide Chairman, Cardiovascular Devices and Diagnostic, of Defendant Johnson & Johnson") "acknowledged" that another company—not Cordis—was marketing and promoting its own biliary stents off-label. TAC ¶ 161. This conduct is facially lawful and shows public disclosure.

(11) at a meeting Relator does not appear to have attended, Rick Anderson (allegedly "Worldwide Franchise Chairman of Defendant Cordis Endovascular") "discussed his strategy to create disease specific marketing groups" and "stated that it was important to obtain appropriate indications for the biliary stents." TAC ¶ 162. This conduct is facially lawful and shows public disclosure.

(12) Cordis marketed its biliary stent systems as vascular devices via its websites, press releases, and various medical journals focused on the treatment of vascular disease. TAC ¶¶ 166-68, 171, 173, 178 & 179. This allegation presents a conclusion.

(13) "upon information and belief" Cordis was sponsoring Dr. Glickman's peripheral training course on his suggestion. TAC ¶ 188. This conduct is facially lawful in part and conclusory without legally sufficient detail.

(14) Cordis provided healthcare providers with reimbursement guidelines that instructed healthcare providers to bill Medicare for placement of an FDA-approved renal stent when using a biliary stent. TAC ¶ 195. This conduct is facially lawful in part and conclusory without legally sufficient detail in part.

(15) Cordis provided healthcare providers with a product catalog that provided information to providers for purchasing endovascular and neurovascular products made by Cordis and identified biliary stent systems as endovascular stents. TAC ¶ 196. This conduct is facially lawful in part and conclusory without legally sufficient detail in part.

a. The Third Amended Complaint Must Be Dismissed Under FRCP 12(b)(6) for Failure to State a Claim Upon Which Relief May Be Granted.

This Court is well aware of the standard of review for FRCP 12(b)(6) motions to dismiss for failure to state a claim upon which relief may be granted. Having conceded that the hospitals and physicians using biliary stents in vascular procedures do so lawfully in connection with medical necessary procedures, Relator seeks to impose liability on the manufacturers that sold the stents for use by the hospitals and physicians, notwithstanding the fact that none of the stent manufacturers submitted any claims and the claims submitted by hospitals and physicians were not actually false or associated with any express or implied false certification to obtain payment for services and procedures. A regulatory violation of the FDCA cannot sustain a False Claims Act action as matter of law because compliance with the FDCA is not a condition of, or material to, payment from federal health care programs.

1. Actual Claim or Statement Falsity.

Relator has not identified any information relevant to the actual claim submitted for reimbursement and his theory cannot be assessed by the Court in the abstract. Cordis contends that the claims for reimbursement of physician services and hospital based procedures that may use a biliary stent involve no false or fraudulent interaction, claim or statement by the hospital or doctor. There must be an underlying false claim or a false statement to get a false claim paid that Cordis "caused" to be submitted. The use of the biliary stent in a vascular procedure does not render the procedure an uncovered service ineligible for reimbursement and is not material to the government's decision to pay the claim. *Stephens*, 664 F. Supp. 2d 1310; *see also Kennedy*, 2008 WL 5211021 (N.D. Ill. 2008) (dismissing False Claims Act action on basis off-label use was not material to government's decision to pay). A claim that accurately and truthfully describes a

patient's condition and treatment is not legally false. *Hutcheson*, 694 F. Supp. 2d at 61-62; *Polanksy*, 2009 WL 1456582, at *7.[16]

2. Express Certification of Compliance for Payment.

In *U.S. ex rel. Thompson v. Columbia/HCA Healthcare*, the Court affirmed the well-recognized principle that regulatory violations alone, or general fraudulent conduct, cannot comprise a False Claims Act violation. 125 F.3d 899 (5th Cir. 1997). The *Thompson* decision also recognized a narrow circumstance in which a hospital or physician health care provider who must directly certify compliance *with a specific regulation* may comprise a False Claims Act violation only if such a certification was an express condition of payment and the certification was materially false to obtain payment. *Thompson, supra,* 125 F.2d at 699. Here, there is no legal dispute that compliance with the FDA 510(k) clearance process or FDA promotional regulations is not an express condition of payment for the hospital or the physician and cannot comprise a basis of derivative or downstream liability for a manufacturer that simply sold product to the hospital for the lawful use by the physician. *Mikes, supra, at* 698; *U.S. ex rel. Landers v. Baptist Memorial Health, 525 F.Supp.2d 972, 978 (W.D. Tenn. 2007)(an express false claim is a claim that falsely certifies compliance with a particular statute as a prerequisite to payment); Hutcheson*, *supra*, 694 F. Supp. 2d at 61-62.

Relator's newly presented anti-kickback count is similarly defective. Relator generically alleges that all defendants provided healthcare providers with "discounts, rebates and other forms

[16] In the context of drug reimbursement, which differs from hospital procedures, some courts have recognized but limited FCA liability to situations in which the drug use for which the claimant seeks reimbursement was previously the subject of an explicit adverse coverage determination by Medicare, or is expressly precluded under an objective Medicaid standard. In other words, truthful claims have been held to be "false" only where the claims were rendered categorically ineligible for reimbursement by a prior coverage determination or other bright-line rule. *U.S. ex rel. Franklin v. Parke-Davis*, 2003 WL 22048255, at *2-3 (D. Mass. 2003); *see also U.S. ex rel. Hess v. Sanofi-Synthelabo, Inc.,* 2006 WL 1064127 (E.D. Mo. 2006*); U.S. ex rel. Rost v. Pfizer, Inc*., 253 F.R.D. 11, 16 (D. Mass. 2008). Compliance with the FDCA promotion regulations, however, is simply not an express condition of payment.

of remuneration" to encourage them to use their biliary stents. TAC ¶¶ 148 & 181-91. Notably, Relator does not assert any specific allegations that Cordis provided any healthcare providers with any discounts or rebates. Relator also does not allege that any of the alleged discounts and rebates offered by defendants actually induced any healthcare provider to submit a false claim for his or her services. These omissions are fatal to the assertion of any viable cause of action against Cordis. *Hutcheson*, 694 F. Supp. 2d at 65-67 (relator's failure to allege that defendant hospital "induced doctors to perform medically unnecessary surgeries for which they sought reimbursement from Medicare" and dismissing claims premised on AKS violations under Rule 12(b)(6) because "[t]he Amended Complaint contains no allegations that the hospitals themselves received kickbacks, or that they knew or should have known about the kickbacks received by the doctors").

Relator asserts only one vague, multiple-hearsay allegation "upon information and belief" that Relator understood from another former Guidant sales representative, Dean DeVries, that Mr. DeVries heard from a vascular surgeon, Dr. Marc Glickman, that Cordis was paying Dr. Glickman various amounts to support his vascular fellowship program and to sponsor his peripheral vascular training courses, in order to secure his "business." TAC ¶ 188. However, Relator fails to allege that any of the discounts, payments, or other remuneration actually caused a single healthcare provider, including Dr. Glickman, to use any of defendants' stents that the kickbacks tainted any healthcare provider's professional judgment, or that such stents were ever used for medically unnecessary surgeries. Indeed, Relator expressly concedes that he "does not challenge the clinical decision of a physician to use a legally marketed medical device for an indication not cleared or approved by FDA when exercising his or her independent judgment under the practice of medicine doctrine." TAC ¶ 14.

As the Court explained in *Hutcheson*, physicians are reimbursed purely for their services and the purchase of medical devices is "not an underlying transaction to the reimbursement request for the doctor." *United States ex rel. Hutcheson v. Blackstone Medical, Inc.* 2010 WL938361, at *15-16 (D. Mass., March 12, 2010). *Id.* at 67. Accordingly, a kickback received by a healthcare provider cannot have caused the submission of a false claim for reimbursement for a medical device unless the healthcare provider was induced "to perform medically unnecessary surgeries for which they sought reimbursement from Medicare," in which case, "the underlying transaction -- the sale of surgical services to a patient -- would have been tainted by a kickback." *Id.* Relator's failure to allege any nexus between the alleged kickbacks and the submission of false claims for any healthcare provider's services and his admission that doctors have properly exercised their own independent judgment in medically necessary stenting procedures are both fatal to his contortionist kickback theory under the FCA. *Kennedy*, 2008 WL 5211021 at *5-6 (assuming compliance with the anti-kickback statute is a prerequisite to hospital reimbursement, relators mere naming of two hospitals as having received grants is insufficient to show a link between off-label marketing activities and a material false claim or false certification submitted by any hospital).

3. Implied Certification of Compliance for Payment.

Relator appears to suggest a theory of *implied* certification of compliance liability based on the alleged regulatory violations and false 510(k) submissions by Cordis to the FDA. The implied certification doctrine, however, is simply not recognized in the Fifth Circuit and cannot form the basis of False Claims Act liability. *U.S. ex rel. Gonzalez v. Fresenius Med. Care*, 2010 WL 1645971, at *11 (W.D. Tex. 2010). Liability may not be implied from regulatory violations for which there is no nexus to an express condition of payment. *In re Genesis Health Ventures,* 272 B.R. 558, 570 (2002) (implied false certification theory only appropriately applies when the

underlying regulation expressly states that the provider must comply to be paid). Accordingly, Cordis cannot as a matter of law have implicitly caused the submission of a false claim or made any material false statement that caused the payment of a false claim.

b. The Third Amended Complaint Must Be Dismissed for Failure to Plead Fraud with Particularity in Violation of FRCP 9(b).

In the Fifth Circuit, it is well established that all claims brought under the False Claims Act must adhere to the strict pleading requirements set forth in Rule 9(b) and a plaintiff must specify, at a minimum, the "who, what, when, where, and how" of the alleged fraud. *U.S. ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 185-86 (5th Cir. 2009); *U.S. ex rel. Willard v. Humana Health Plan of Tex., Inc.*, 336 F.3d 375, 384 (5th Cir. 2003); *Thompson*, 125 F.3d at 903. Here, the Relator's complaint allegations fail in material particularity or causation under § 3729(a)(1) for false claims or under § 3729(a)(2) for false statements.

1. Relator's Derivative False Claim Allegations Fail.

Other federal courts have considered whether an off-label promotion violation may comprise a False Claims Act violation and, if so, the pleading particularity required. Foremost, an allegation of off-label promotion that merely results in a claim that is reimbursable is not actionable. *U.S. ex rel. Franklin v. Parke-Davis, Div. of Warner-Lambert Co.,* 2003 WL 22048255 (D. Mass.). There must be some allegation that sufficiently shows an actual false or fraudulent claim and the factual mechanics of how Cordis caused the submission of a false claim. Subjective conclusions, moreover, are not sufficient to sustain the pleading burden. In *Hopper v. Solvay Pharmaceuticals, Inc.*, the court affirmed the dismissal of a False Claims Act *qui tam* on the basis of alleged off-label promotion violations that comprised an alleged marketing campaign to convince doctors to prescribe Marinol for off-label uses. 588 F.3d 1318 (11th Cir. 2009). The *Hopper* complaint did not identify a single physician who wrote a prescription *with knowledge* of

having falsely submitted a claim to the government for reimbursement. Rather, "the Complaint piles inference upon inference to suggest that Solvay's marketing campaign influenced some unknown third parties to file false claims. We cannot conclude that the Complaint satisfies the particularity requirements of Rule 9(b) by offering some indicia of reliability . . . of an actual false claim for payment being made to the Government." *Id.* at 1326.

Further instructive is another recently dismissed case, *U.S. ex rel. Polansky v. Pfizer, Inc*., where the Relator alleged that Pfizer pursued an off-label marketing scheme that caused federal and state health programs to pay false or fraudulent claims reimbursing prescriptions for Lipitor other than those indicated on its label. 2009 WL 1456582 (E.D.N.Y. May 22, 2009). Relator did not identify any false claims or physicians who were induced to write a prescription for an off-label use. "The essence of his claim is that Pfizer advocated that Lipitor be prescribed in cases in which its use was not recommended by the [applicable] Guidelines. This is insufficient to satisfy Rule 9(b)." *Id.* at *5.

Like the *Pfizer* and *Solvay* cases, in this action, Relator does not provide legally sufficient details about any false claims, nor does he name a single physician who was induced to use a biliary stent because of the defendants alleged off-label promotion activities.

2. Relator's Derivative False Statement Allegations Fail.

In order to satisfy FRCP 9(b) when pleading a false statement count under 31 U.S.C. § 3729(a)(2), a Relator must show "that the defendant made a false record or statement for the purpose of getting *a false or fraudulent claim* paid or approved by the Government . . .[he] must prove that the defendant intended that the false record or statement be material to the Government's decision to pay or approve the false claim." *Rafizadeh,* 553 F.3d at 874 (emphasis added and citations omitted). Both the statement and the claim must be false. *U.S. ex rel. Mikes v. Strauss,* 274 F.3d 687 (2d Cir. 2001). Relator alleges that Defendants made two false

statements: (1) that they certified to the FDA that the stents were intended for biliary use only, TAC ¶¶ 4B, 11-12, 77-82; and (2) that the Defendants "expressly or by implications" made false representations to physicians that the biliary stents were FDA approved vascular stents, TAC ¶¶ 4C, 13-13AA. So, what are the representations? To whom were they made? When were they made? How is the alleged statements material to the payment of an underlying false claim? Relator's unsegregated and non-specific allegations simply do not satisfy the requirements of FRCP 9(b) or present the level of detail in which this Court could even undertake an assessment of compliance with the heightened pleading standard.

Similar to other courts that have assessed conclusory, unsegregated and non-specific allegations of off-label promotion and kickbacks, and, found the allegations insufficient; this Court should conclude there are no details in this action to "strengthen the inference of fraud beyond possibility." *Rost*, 507 F.3d at 733 (affirming dismissal off-label promotion qui tam under FRCP 9(b) in face of litany of alleged marketing activities unconnected to the submission of any false claim); *see also Poteet*, 604 F. Supp. 2d at 324 (dismissing multi-defendant *qui tam* where marketing activities asserted as kickbacks were publicly disclosed and unconnected to submission of false claims under FRCP 9(b)); *Radcliffe*, 582 F. Supp. 2d 766 (dismissing qui tam allegations of off-label promotion under FRCP 9(b) where no detail of a single instance is alleged that manufacturer's "encouragement" to physicians to prescribe medication reimbursed by Medicaid actually influenced a single physician to prescribe drug based on alleged encouragement).

V. Johnson & Johnson and Cordis Endovascular Are Improper Parties.

Relator fails to state a claim against Johnson & Johnson and his claims should be dismissed with prejudice. *In re Pharma. Indus. Average Wholesale Price Litig.*, 538 F. Supp. 2d at 391 (dismissing FCA claim against corporate parent Johnson & Johnson where relator failed

to support theory of piercing the corporate veil); *U.S. ex rel. West v. Ortho-McNeil Pharma., Inc.*, 2007 WL 2091185, at *5 (N.D. Ill. 2007) (dismissing FCA off-label marketing claims against corporate parent Johnson & Johnson because relator had pleaded no facts to support a piercing the corporate veil theory). Not a single wrongful act alleged in the Complaint is attributed to Johnson & Johnson. Instead, the Complaint alleges that Defendant Cordis is the alter ego of its parent Johnson & Johnson. To support this contention, the Complaint avers in conclusory fashion that Johnson & Johnson dominates and controls the policies of Cordis. TAC ¶¶ 26-27. The Complaint alleges no facts to support the assertion that Johnson & Johnson "dominates and controls" Cordis or its policies—indeed, it alleges no further facts regarding Johnson & Johnson's actions or relationship with Cordis at all.

The only basis for Relator's inclusion of Johnson & Johnson in this action is its alter ego allegation and Johnson & Johnson is incorporated in New Jersey, this Court must apply New Jersey law to its analysis of the sufficiency of Relator's allegations. *In re Moore*, 379 B.R. 284, 289 n.3 (Bkrtcy. N.D. Tex. 2007) (holding that courts are required to apply the law of the state of incorporation to corporate veil issues) (citing *Jefferson Pilot Broadcasting Co. v. Hilary & Hogan, Inc.*, 617 F.2d 133, 135 (5th Cir. 1980). As a general matter, a parent corporation is not liable for the acts of its subsidiaries and "[l]iability will not be imposed on the parent corporation merely because of its ownership of the subsidiary nor because directors of the parent corporation also serve as directors of the subsidiary." *Portfolio Fin. Servicing Co. ex rel. Jacom Computer Servs., Inc. v. Sharemax.com, Inc.*, 334 F. Supp. 2d 620, 626 (D.N.J. 2004). The only way to overcome this "deeply ingrained" principle is to make a showing of a basis to pierce the corporate veil. *Id*.

In order to state a claim for piercing the corporate veil under New Jersey law:

> a plaintiff must allege that the parent completely dominates the finances, policy, and business practice with respect to the subject transaction to such a degree that the subsidiary has no separate mind, will, or existence of its own. The relevant factors in this inquiry include:
>
> Gross undercapitalization . . . failure to observe corporate formalities, non-payment of dividends, the insolvency of the debtor corporation at the time, siphoning of the funds of the corporation by the dominant stockholder, non-functioning of other officers or directors, absence of corporate records, and the fact that the corporation is merely a façade for the operations of the dominant stockholder or stockholders

Ramirez v. STi Prepaid LLC, 644 F. Supp. 2d 496, 507 (D.N.J. 2009) (quoting *Craig v. Lake Asbestos of Quebec, Ltd.*, 843 F.2d 145, 150 (3d Cir. 1988) (applying New Jersey law) (internal quotations omitted). The Relator simply fails to allege any of the enumerated factors that could support such a conclusion. *Id.*; *see also Pathfinder Mgmt., Inc. v. Mayne Pharma PTY*, 2008 WL 3192563, at *6 (D.N.J. Aug. 5, 2008) (dismissing claim against corporate parent rejecting plaintiff's argument that alleging an alter ego theory is sufficient without pleading any of its elements); *U.S. ex rel. Pilecki-Simko v. The Chubb Institute*, 2010 WL 1076228, at *13 (D.N.J. 2010).[17] Accordingly, the claims against Johnson & Johnson must be dismissed.

For all the reasons cited herein, and the attached Joint Defense Exhibit, Cordis urges this Court to grant its Motion to Dismiss and all requested relief in its entirety.

[17] *See also United States ex rel. Westmoreland v. Amgen, Inc.*, 2010 WL 1634315, at *13 (D. Mass. Apr. 23, 2010); *United States ex rel. Pfeifer v. Ela Medical, Inc.*, 2010 WL 1380167, at *14 (D. Colo. Mar. 31, 2010); *United States ex rel. Hockett v. Columbia/HCA Healthcare Corp.*, 498 F. Supp. 2d 25, 59-60, 61 (D.D.C. 2007); *United States ex rel. Fent v. L-3 Comms. Aero Tech LLC*, 2007 WL 3485395, at *3-4 (N.D. Okla. 2007); *United States ex rel. Kneepkins v. Gambro Healthcare, Inc.*, 115 F. Supp. 2d 35, 39-40 (D. Mass. 2000); (all dismissed corporate parents in *qui tam actions).*

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing document was served upon all counsel of record via ECF electronic filing on July 16, 2010.

/s/ Kathleen Dermott
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